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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,610	01/11/2001	Jonathan S. Stamler	Duke File No. 1838	8014

7590 05/19/2003

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EXAMINER
TELLER, ROY R

ART UNIT	PAPER NUMBER
1654	13

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/757,610	STAMLER ET AL.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This office action is in response to Paper No: 12, received 2/28/03.

Claims 8-14 will be examined

Double Patenting

Upon further consideration, the nonstatutory double patenting rejection of claims 8-14 is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Upon further consideration, the rejection of claims 8-14 are rejected under 35 U.S.C. 112, first paragraph, made in Paper No: 9 (mailed 10/21/02) is reinstated for the reasons of record and for the additional reasons set forth *infra*. Applicant's arguments will be addressed as they pertain to the current grounds of rejection. The specification, while being enabling for administering an

inhibitor of glutathione-dependent formaldehyde dehydrogenase does not reasonably provide enablement for killing or reducing the growth of pathologically proliferating mammalian cells *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification fails to provide information that would allow the skilled artisan to practice the invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CFAC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Foreman*, 230 USPQ 546 (Bld Apls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction and guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art,

8) the breadth of the claims.

The quantity of experimentation necessary would be undue. The working examples lack sufficient data. Therapies involving cancer and pathologically proliferating cells are unpredictable (see Dermer, Biotechnology, March 12, 1994, vol. 12, pp.320). In Dermer, column 1, 3rd paragraph "petri dish cancer is really a poor representation of malignancy, with characteristics profoundly different from the human disease." The amount of direction and

guidance provided is lacking. The working examples lack sufficient data to understand if the clinical results will invariably occur. The specification does not teach how to assess and/or modify each of the variables necessary for the therapy to work.

The working examples provided lack sufficient data to determine how to avoid the pitfalls in the process of using the therapy.

The nature of the invention is concerned with providing therapy for pathologically proliferating mammalian cells. The specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to provide effective therapy for pathologically proliferating mammalian cells.

The state of the prior art is unpredictable when involved with therapies for cancer and pathologically proliferating mammalian cells. (Dermer, Biotechnology, March 12, 1994, vol. 12, pp.320).

The relative skill of those in the art would be a practicing MD skilled in clinical research.

The predictability of the art is that cancer therapies and therapies for pathologically proliferating mammalian cells are unpredictable.

The breadth of the claims- the rejected claims are directed to therapies for cancer and pathologically proliferating mammalian cells but the specification does not so demonstrate.

In consideration of each of factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Applicant's arguments filed 11/23/02 are not persuasive for the following reasons. Based on the teachings of unpredictability regarding *in vivo* therapy which are taught in the prior art, persons skilled in the art would not associate *in vitro* results with *in vivo* therapeutic efficacy. Applicant's specification fails to contain sufficient disclosure to overcome the teachings of unpredictability which are found in the art. *Ex parte Balzarini* 21 USPQ2d 1892 (BdPatAppl &Int. 1991).

Conclusion

All claims are rejected. Due to the new grounds of rejection herein, this action is made nonfinal.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RT
1654
5/13/03

RT

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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